ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

Statement of

Lisa Swirsky

Senior Policy Analyst

before the

United States House of Representatives

Committee on Energy and Commerce

on

Reauthorization of MDUFA: What It Means for Jobs, Innovation and Patients

February 15, 2012

My name is Lisa Swirsky, and I am a Senior Health Policy Analyst at Consumers Union. Consumers Union (CU) is the policy and advocacy arm of Consumer Reports, the nonprofit publisher of *Consumer Reports* magazine and *Best Buy Drugs*. Consumers Union's Safe Patient Project, which has successfully organized consumers on patient safety issues such as hospital-acquired infections over the past eight years, has recently launched a campaign to improve medical device safety. CU is a member of the Patient, Consumer and Public Health Coalition, which represents a broad group of academics, think tanks, scientific integrity organizations and consumer groups concerned about the safety and efficacy of drugs and devices. Many of the concerns we have with the draft agreement between FDA and the industry on medical device legislation reflect the concerns of a broader community of public interest organizations committed to changing the Medical Device User Fee Act (MDUFA) so it will provide timely access to safe and effective medical devices.

Medical devices, like eyeglasses and contact lenses, are a part of our everyday lives and are a growing part of the health care we receive. Complex devices like artificial hip joints, surgical mesh, and cardiovascular stents, are permanently implanted and can be essential for sustaining life. These high-risk devices can cause serious harm if they break, leak, stop functioning or disintegrate. When an implanted device is recalled or removed from the market, patients cannot simply stop using them. Removal of the device requires surgery, sometimes multiple surgeries, and it may take months or years to repair the damage done by the device. Many patients are permanently disabled due to complications from a device. Even low-risk devices, like contact lens solution and alcohol swabs have recently caused patients harm that could have been prevented.

Unlike prescription drugs, most devices do not require proof that they have been tested on humans and found to be safe and effective prior to being cleared by the FDA for distribution or sale. Further, the system for monitoring and tracking what happens with devices once they are on the market is weak and does not adequately protect people using them.

Any reauthorization of MUDFA should improve safety and the current pathways followed to bring devices onto the market and improve the system of monitoring devices after being implanted in patients or sold to consumers. For example two specific policies that Congress should consider are: (1) legislation ensuring that devices that have proven faulty can not be used as the basis for clearing other subsequent devices; and (2) legislation providing FDA authority to require post market studies when it deems necessary to ensure the safety of devices.

Our priority is that these devices work and don't hurt people. With proper resources, we can have a streamlined, timely system without sacrificing safety.

Contrary to public perception, the device industry is far less regulated than the drug industry. Consumers Union urges Congress to take a balanced approach to reauthorizing the Medical Device User Fee program, focusing on the real need to keep deficient and dangerous devices off the market while providing timely access to safe and effective devices. Safety failures resulting from failures in the device regulatory system, particularly the problematic 510(k) process, have caused serious harm to real consumers.

Consider the case of Lana Keaton, a healthy woman who was treated for incontinence, a common condition for middle aged women. She went in for surgery for insertion of a synthetic mesh bladder sling, a product cleared through the 510(k) system. She awoke from surgery in extreme pain. The synthetic mesh used in her surgery has caused severe complications and pain that has required her to undergo 17 additional surgeries. CU urges Congress to remember the experiences of hundreds of thousands of people like Lana who have been injured by defective devices as it considers reauthorization of the medical device user fee program.

CU has reviewed provisions of the agreement as described in the minutes from the FDA's January 31st meeting with industry. We anticipate having the opportunity to publicly comment on a more detailed description of the agreement. Nevertheless, Consumers Union offers the following comments and concerns on what we know now.

User Fee Adequacy

The fees paid by medical device makers are currently so modest, that even doubling of the fees is a small price to pay when considering that these devices may make companies millions to billions of dollars. In 2012, the fees should be increased to reflect the level of work required by FDA to review and ensure the long-term safety of complex devices.

During the course of negotiations with industry, the FDA indicated that it needed resources of between $770 million to $ 1.15 billion to implement the performance goals desired by industry.[1] The $595 million allocated under the agreement falls far short of FDA's requests. FDA has said it will scale back it's commitments to industry-requested enhancements in light of the lower than requested user fee.[2] However some of these process improvements, such as additional pre-submission steps, remain in the agreement without any dedicated funding and will have to be paid for with base resources. Without adequate funding, we are concerned that FDA will be pressured to take on new tasks for the industry, leaving fewer resources available to fulfill its current responsibilities and to ensure the safety of medical devices. To the extent that Congress decides to require the FDA to meet these new industry-requested responsibilities that are not paid for by user fees, it must provide dedicated funding to the agency for these tasks.

Performance Goals

We remain concerned about the implied quid pro quo created by the user fee system which, in exchange for industry fees, places an emphasis on speedier review times as an end to itself without ensuring that the safety and effectiveness of devices aren't sacrificed. When device applications are reviewed and processed within a reasonable timeframe because the application is sound and the device is safe and effective that is a win for both consumers and industry. But speeding the introduction of devices to market only makes sense in the context of a system that assures that these devices are safe and work in a way that advances the public health.

---

[1] Food and Drug Administration, Minutes from Negotiation Meeting on MDUFA III Reauthorization, October 31, 2011.

[2] Food and Drug Administration, Minutes from Negotiation Meeting on MDUFA III Reauthorization, January 31, 2012.

Currently the 510 (k) process, through which 90 percent of regulated devices are currently cleared, merely tests whether or not a device is substantially equivalent to something on the market.

The chart below shows the emphasis in the agreement on speedy review of medical devices. For all three of the device approval tracks the agreement commits FDA to at least a 90 percent approval rate in five years. Absent from the agreement is any commensurate commitment to ensuring that these goals be met without compromising safety or efficacy.

MDUFA III Goals for Percent of Applications Approved as Agreed to by Industry and FDA			
	Goals for Pre Market Approval of devices that go to panel (320 FDA days)	Goals for Pre Market Approval that don't go to panel (180 FDA days)	510(k) Clearance
FY 13	50%	70%	91%
FY 14	70%	80%	93%
FY 15	80%	80%	95%
FY 16	90%	90%	95%
FY 17	90%	90%	95%
Source: FDA minutes from January 31, 2012 meeting with industry to negotiate MDUFA agreement.			

The agreement in principle reached by the FDA and industry illustrates this inherent problem with a user fee structure. At a time when the device industry has seen large scale safety failures of some of it products, such as surgical mesh and metal-on-metal hips, it is troubling that the main focus of conversations between industry and the agency that regulates it is on speeding up review times. Instead, the focus should be on improving the review process to ensure that it provides timely access to high quality devices that improve the public health while assuring safety. The word "safety" does not appear once in the minutes from the meeting where industry and FDA came to agreement. This is a striking omission given recent notable safety lapses by the device industry.[3]

There is no mention in the agreement that these time goals are conditioned on the overall quality of the products, the complexity of the products, the benefit of the product to consumers, or any other factors that may be relevant to protecting the public health.

Even more worrisome, the agreement in principle references total time to decision goals (see chart below) based on calendar years in addition to the goals based on FDA days. This

[3] Food and Drug Administration, Minutes from Negotiation Meeting on MDUFA III Reauthorization, January 31, 2012.

additional metric raises troubling safety and efficacy concerns for consumers. Current performance goals stop the clock when the FDA sends an application back to a device manufacturer when the agency needs additional information. Under the agreement, the FDA and industry agree to total time to decision goals based on calendar years. This construct keeps FDA on the clock even when it has to send back an incomplete application to the manufacturer. This places constraints on the ability of the FDA to seek additional information with respect to safety and efficacy once a completed application has been submitted. CU opposes any provision that would limit FDA's ability to ask for more information when needed to ensure the safety and efficacy of devices.

MDUFA III Shared Outcome Goals for Total Time to Decision as Agreed to by FDA and Industry

	PMA	510(k)
FY 13	395 calendar days	135 calendar days
FY 14	395 calendar days	135 calendar days
FY 15	390 calendar days	130 calendar days
FY 16	390 calendar days	130 calendar days
FY 17	385 calendar days	124 calendar days

Source: FDA minutes from January 31, 2012 meeting with industry to negotiate MDUFA agreement.

Benefit Risk Determinations

We have further concerns about provisions in the agreement that call for incorporating the patient perspective into risk benefit considerations. The industry wants groups that represent patients with a specific disease to represent the patient perspective. However, many of these patient groups are heavily funded by industry and could misrepresent the public perspective. The FDA must commit to finding patient voices free from conflicts with industry to inform risk benefit considerations. Patient representatives used for these purposes should be held to conflict of interest standards and should be required to disclose any financial ties with industry.

Pre-submission Process

The FDA and industry have agreed to administrative improvements to the pre-submission process in order to bring greater consistency to the process and to provide industry with greater clarity about the FDA's expectations prior to submitting a device application. In principle, we agree that improving the quality of submissions is an appropriate way to reduce review times.[4]

During negotiations with industry the FDA proposed specific timelines and goals for different steps in the pre-submission process. The agency also proposed publishing guidance

[4] Food and Drug Administration, Minutes from Negotiation Meeting on MDUFA III Reauthorization, January 31, 2012.

clarifying submission acceptance criteria, so that the agency is only reviewing completed submissions. In patient and consumer group stakeholder meetings, the FDA indicated that the clock will start running with respect to time goals only after it receives a completed submission. The details of the formal agreement are not yet available, but in principle we support this provision of the agreement. This is consistent with FDA's focus on a shared commitment with industry to reduce review times that includes industry responsibility to improve the quality of submissions, as well as administrative efficiencies by the FDA.

We are supportive of efforts by the FDA to improve the quality of submissions and provide greater clarity to the industry, but we are disappointed in the lack of designated user fees to fund pre-submission meetings. Without new resources for these improvements, this amounts to an unfunded mandate on an agency already struggling to meet its current responsibilities. Unfortunately, the industry has not agreed to additional user fees to pay for improvements to the pre-submission process. As a result, the agency states that it has scaled back plans for improvements to the pre-submission process to reflect the level of user fees the industry is willing to pay. Specifically, FDA has removed specific timelines and goals for different steps in the process. However, the agency still commits to improving the pre-submission process using its base resources.

Involving Consumers in the Process

As Congress considers reauthorization of the Medical Device User Fee Act, we urge it to provide a direct seat at the table for consumers in future reauthorization negotiations. While these parallel stakeholder meetings with patient and consumer groups were an advancement over previous reauthorization processes, they still keep consumers at arm's length from negotiations that have significant implications for the public health. Despite the participation of consumer groups in stakeholder meetings with FDA, concerns raised in these meetings do not appear to have impacted any of the provisions in the agreement in principle.

The FDA and Congress have an opportunity to fix a system that is currently flawed because it allows too many unsafe medical devices to enter the market. In the next five years, the use of medical devices – especially implants – will increase significantly more than in the past five years. Yet, our system of review fails to ensure safety up front and there is no workable early warning system to adequately identify problems with devices after they have been implanted in patients. Americans are counting on their representatives to strengthen the law to ensure that patient safety isn't sacrificed in the drive to speed up the approval of new medical devices.